K000568

AUG 4 2000

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd
Indianapolis IN 46250
(317) 576-3544

Contact person: Kay A. Taylor

Date prepared: February 18, 2000

Predicate device

The HDL Cholesterol Plus is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the Boehringer Mannheim HDL Cholesterol (K963213).

Device name

Proprietary name: Roche HDL Cholesterol Plus

Common name: HDL Cholesterol test

Classification name: LDL & VLDL Precipitation, Cholesterol via Esterase Oxidase, HDL

Device description

The HDL Cholesterol Plus is a homogeneous enzymatic colorimetric test. Results are determined photometrically by measuring the color intensity of a dye, which is generated during the reaction and is directly proportional to the cholesterol concentration of the sample.

1st incubation (5 min),
2nd incubation (5 min),

510(k) Summary, continued

Intended use	For the direct quantitative determination of high-density lipoprotein cholesterol (HDL-cholesterol) in serum and plasma.
Indication for use	Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Roche HDL-cholesterol plus reagents are intended for use on automated clinical chemistry analyzers.
Substantial equivalence	The HDL Cholesterol Plus is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the HDL Cholesterol currently marketed for use on the Roche/Hitachi family of clinical chemistry analyzers (K963213).

510(k) Summary, continued

Substantial equivalence – similarities

The following table compares the HDL Cholesterol Plus with the predicate device.

Feature	Modified device	Predicate Device
Intended use	For the direct quantitative determination of high-density lipoprotein cholesterol (HDL-cholesterol) in serum and plasma	For the quantitative determination of high-density lipoprotein cholesterol (HDL-cholesterol) in serum and plasma
Indication for use	Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.	Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.
Sample type	human serum and plasma	human serum and plasma
Assay principle	Cholesterol esterase / Cholesterol oxidase	Cholesterol esterase / Cholesterol oxidase
Calibrator	C.f.a.s. HDL /LDL-C Plus Calibrator	C.f.a.s. HDL-C Calibrator or other NIST traceable calibrator
Recommended quality control	Precinorm L Special Lipid Control / Precipath HDL/LDL Control	Precinorm L Special Lipid Control / Precipath HDL/LDL Control
Measuring Range	3- 120 mg/dl	3 – 150 mg/dl
Expected values	NCEP guidelines < 35 mg/dL Low HDL Cholesterol (major risk factor for CHD) > 60 mg/dL High HDL Cholesterol (negative risk factor for CHD)	NCEP guidelines < 35 mg/dL Low HDL Cholesterol (major risk factor for CHD) > 60 mg/dL High HDL Cholesterol (negative risk factor for CHD)

510(k) Summary, continued

Substantial equivalence – differences

The following table compares the HDL Cholesterol Plus with the predicate device.

Feature	Modified device	Predicate Device
Instrument	Olympus AU 5200 / 5000 / 800 Analyzers	Roche/Hitachi family of analyzers
Application Information	Sample Vol = 4µl R1 Vol = 300µl R2 Vol = 100µl Wavelength = • 1. 600nm • 2. 660nm Reaction Temp = • 37°C Incubation Time = • R1 – 5 min • R2 – 5 min	Sample Vol = 4µl R1 Vol = 300µl R2 Vol = 100µl Wavelength = • 1. 700nm • 2. 600nm Reaction Temp = • 37°C Incubation Time = • R1 – 5 min • R2 – 5 min
R1 reagent formulation	• g/L sulfated – cyclodextrin • 0.7 g/L dextran sulfate • 7.0 g/L magnesium sulfate • 0.3 g/L HDAOS • 2 g/L MOPS buffer, pH 7.0 • 3 kU/L ascorbate oxidase • 5 kU/L peroxidase liquid	• 0.5 mmol/L sulfated – cyclodextrin • 0.5 g/L dextran sulfate • 2 mmol/L magnesium chloride • 0.3 g/L EMSE • 30 mmol/L MOPS buffer, pH 7.0 • Preservative • Liquid

Substantial equivalence – differences, con't

The following table compares the HDL Cholesterol Plus with the predicate device.

Feature	Modified device	Predicate Device
R2 reagent formulation	• 3 /gL PIPES buffer, pH 7.0 • 0.8 kU/L PEG – cholesterol esterase • 5.3 kU/L PEG cholesterol oxidase • 16 kU/L peroxidase • 0.4 g/L 4 – aminophenazone • preservative • liquid	• > 1 kU/L PEG cholesterol esterase • > 5.6 kU/L PEG cholesterol oxidase • > 30 kU/L peroxidase • 0.5 g/L 4 – aminophenazone • 30 mmol/L MOPS, pH 7.0 • detergent, preservative • lyophilizate

Substantial equivalence – performance characteristics

The Performance characteristics of the HDL Cholesterol Plus and the predicate device are compared in the table below.

Feature	Modified device	Predicate Device
Within Run precision (%CV)	2.65% at 31.5 mg/dl 2.09% at 45.7 mg/dl 2.99% at 31.7 mg/dl	0.73% at 21.42 mg/dl 0.88% at 45.24 mg/dl 0.92% at 62.54 mg/dl
Total precision (%CV)	2.85% at 31.5 mg/dl 2.14% at 45.7 mg/dl 3.30% at 31.7 mg/dl	7.6% at 21.42 mg/dl 2.0% at 45.24 mg/dl 4.1% at 62.54 mg/dl
Accuracy	Method comparison of HDL Cholesterol (lyophiliate) on the Olympus AU5000(Y) to the HDL Cholesterol Plus (liquid) on the Olympus AU5000(X). Slope = 0.94 Intercept = 1.56 r = 0.996	Method comparison of HDL cholesterol (lyophiliate) on Roche/Hitachi 717(Y) to phosphotungstate precipitation method(X) on Roche/Hitachi 717 Slope = 1.02 Intercept = 0.12 r = 0.95
On-board stability	28 days at 2-8°C	28 days at 2-12°C
Calibration frequency	• with every new lot • as required following quality control procedures	• Std 1: Calibrate daily or with a bottle change • Std 2: Calibrate with a reagent lot change

Substantial equivalence – performance characteristics

The Performance characteristics of the Roche HDL Cholesterol Plus and the predicate device are compared in the table below.

Feature	Modified device (additional applications from labeling)	Predicate Device (labeling submitted with K963213)
Limitations	• No interference from unconjugated bilirubin up to an I index of 57.7 or from conjugated bilirubin up to an I index of 64.0. • No interference from hemoglobin up to an H index of 1000. • No interference from Intralipid up to an L index of 1500. • No significant interference from native triglycerides up to a concentration of 1500 mg/dl.	• No interference from bilirubin up to an I index of 65. • No interference from hemoglobin up to an H index of 1000. • No interference from Intralipid up to an L index of 600. • This procedure not suitable for determination of free cholesterol.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 4 2000

Ms. Kay A. Taylor
Regulatory Affairs, Laboratory Systems
Roche Diagnostics Corporation
9115 Hague Road
PO Box 50457
Indianapolis, Indiana 46250-0457

Re: K000568
Trade Name: HDL Cholesterol Plus
Regulatory Class: I Reserved
Product Code: LBT
Dated: July 7, 2000
Received: July 10, 2000

Dear Ms. Taylor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): N/A K000568

Device Name: HDL Cholesterol Plus

Indications For Use: For the direct quantitative determination of high-density lipoprotein cholesterol (HDL-cholesterol) in serum and plasma. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Roche HDL-cholesterol plus reagents are intended for use on automated clinical chemistry analyzers.

Dean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000568

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)